UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,792	02/20/2004	Geoffrey N. Holland	7135USO6	7179

41155 7590 04/14/2009

BRIAN R. WOODWORTH
275 N. FIELD DRIVE
DEPT. NLEG BLDG H-1
LAKE FOREST, IL 60045-2579

EXAMINER	
RINES, ROBERT D	

ART UNIT	PAPER NUMBER
3686	

MAIL DATE	DELIVERY MODE
04/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,792	HOLLAND ET AL.	
	Examiner	Art Unit	
	R. David RINES	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20090218*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 30 December 2008. It is noted that this application benefits from Provisional Patent Application Serial Nos. 60/509404 and 60/527,583 filed 7 October 2003 and 5 December 2003, respectively. The Information Disclosure Statement filed 18 February 2009 has been entered and considered. Claims 1, 5, and 12 have been amended. Claims 1-12 are pending.

Rejections of claims 1-12 are maintained as set forth in the previous Office Action mailed 30 June 2008, herein incorporated by reference. Applicant's amendments to claims 1, 5, and 12 are addressed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[2] Claims 1-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Butterfield et al. (United States Patent Application Publication #2004/0193453) in view of DeLaHuerga (United States Patent Application Publication #2002/0038392).

As per (currently amended) claim 1, Butterfield et al. disclose a method for auto-associating a medical device with a patient, comprising: equipping a patient with a patient transmitter/receiver chip having a patient ID number, capable of short-range transmission (Butterfield et al.; paragraphs [0044] [0061] [0064] *see patient transmitter/RFID); supplying a medical device equipped with a device transmitter/receiver chip, capable of short-range transmission (Butterfield et al.; paragraphs [0015] [0044][0066][0067] *see RFID equipped IV bag); placing the medical device and the patient in proximity (Butterfield et al.; paragraphs [0047] [0048] [0069]); transmitting a request for patient ID to the patient transmitter/receiver chip from the device transmitter/receiver chip (Butterfield et al.; paragraphs [0037] [0046] [0069] *see interrogation of patient device); transmitting the patient ID number to the device transmitter/receiver chip from the patient transmitter/receiver chip (Butterfield et al.; paragraph [0069]); and sending the patient ID number to a medication management unit from the medical device (Butterfield; paragraph [0069] *see transmission and matching of patient ID from bag to pump).

Butterfield et al. disclose passive linking between each of the transponder equipped devices and accordingly fail to explicitly recite commands to initiate the connection and transfer of data.

However, it is well known in the art to utilize manual commands to initiate data transfers and wireless connections (DeLaHuerga; paragraphs [0210]-[0213]).

Applicant has amended claim 1 with respect to the transmission of data to further specify "…transmitting the patient ID number in an airborne response directly to the device…"

As per this element, while Butterfield et al. disclose the transmission of the patient ID to the IV reservoir (i.e., medical device), Butterfield et al. fail to disclose wireless or "airborne" transmission of the patient ID number.

However, it is well known in the art to utilize manual commands to initiate data transfers and wireless connections (DeLaHuerga; paragraphs [0210]-[0213]).

It would have been obvious to one of ordinary skill in the art to have incorporated well known features of patient associated medical device controls, such as command driven functions as presented by DeLaHuerga in to the configuration disclosed by Butterfield et al. with the motivation of providing an accurate simple IV linking and de-linking protocol and simpler interfacing for monitoring and system settings (DeLaHuerga; paragraph [0029]).

As per claim 2, Butterfield et al. disclose a method further comprising the step of: associating the medical device only to the patient based on the patient ID number sent to the medication management unit (Butterfield et al.; paragraphs [0052] [0055]).

As per claim 3, DeLaHuerga discloses dissociating the medical device from the patient based on a command from a user (DeLaHuerga; paragraph [0166]).

As per claim 4, Butterfield et al. disclose a method further comprising the step of: matching the patient ID number with a medication order prescribed for a patient at the medication management unit (Butterfield et al.; paragraphs [0053] [0055] [0069]).

As per (currently amended) claim 5, Butterfield et al. disclose a method wherein the medical device is a first medical device and the device transmitter/receiver chip is a first device transmitter/receiver chip (Butterfield et al.; paragraph [0069] *see fluid container transponder), and further comprising the steps of: placing a second medical device in proximity to the patient (Butterfield et al.; paragraph [0069] *see pump transponder); supplying the first device transmitter/receiver chip with a first device ID number, and the second device transmitter/receiver chip with a second device ID number (Butterfield et al.; paragraph [0069]); transmitting a request for device ID command to the second device transmitter/receiver chip from the first device transmitter/receiver chip; transmitting the second device ID number to the first device transmitter/receiver chip from the second device transmitter/receiver chip

(Butterfield et al.; paragraph [0068][0069]); and placing the second device ID number in a memory of the first medical device (Butterfield et al.; paragraphs [0068] [0069] *see bag transponder programs pump parameters).

Applicant has amended claim 5 to reflect the "airborne" transmission of data presented in claim 1 as presently amended. This limitation is addressed as presented in the rejection of claim 1 above.

As per claim 6, DeLaHuerga disclose a method further comprising the step of: sending the patient ID number from the first medical device to the second medical device (Butterfield et al.; paragraphs [0068] [0069]).

As per claim 7, DeLaHuerga disclose a method further comprising locking the medical devices to a specific patient ID number and not associating the medical devices with another patient ID (DeLaHuerga et al.; paragraph [0166] *note: DeLaHuerga associates the pump exclusively with only one patient).

As per claim 8, DeLaHuerga disclose a method further comprising locking the patient ID with a specific medical device and not associating the patient ID with other medical devices (DeLaHuerga et al.; paragraph [0166] *note: DeLaHuerga associates the pump exclusively with only one patient).

As per claim 9, DeLaHuerga disclose a method further comprising the step of: associating the medical devices only to the patient based on the patient ID number sent to the medication management unit (DeLaHuerga et al.; paragraph [0166] *note: DeLaHuerga associates the pump and IV bags exclusively with only one patient).

As per claim 10, DeLaHuerga disclose a method further comprising the step of: dissociating the medical devices from the patient based on a command from a user (DeLaHuerga; paragraph [0166]).

As per claim 11, Butterfield et al. disclose a method further comprising the step of: matching the patient ID number with a medication order prescribed for a patient at the medication management unit (Butterfield et al.; paragraph [0069]).

Regarding claims 2-11, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claims 2-11 and are herein incorporated by reference.

As per (currently amended) claim 12, Butterfield et al. disclose a medication management system for auto-associating a medical device with a patient, comprising: a patient transmitter/receiver chip having a patient ID number, capable of short-range transmission and adapted to be secured to a patient (Butterfield et al.; paragraphs [0044] [0061] [0064] *see

patient transmitter/RFID); a medical device having a device transmitter/receiver chip capable of short-range transmission (Butterfield et al.; paragraphs [0015] [0044][0066][0067] *see RFID equipped IV bag, a processor and a memory coupled to the processor, the memory containing programming code executed by the processor to: transmit a request for patient ID command to the patient transmitter/receiver chip from the device transmitter/receiver chip (Butterfield et al.; paragraphs [0037] [0046] [0052] [0069] *see interrogation of patient device and optional use of an additional programmer paragraph [0052]), and send any patient ID number received by the medical device to a medication management unit (Butterfield; paragraph [0069] *see transmission and matching of patient ID and bag to pump *Examiner considers the IV pump to be a form of "medication management unit); and wherein the patient transmitter/receiver chip transmits the patient ID number to the device transmitter/receiver chip in response to the request for patient ID command when the patient transmitter/receiver chip is within proximity to the medical device sufficient to receive the request for patient ID command (Butterfield et al.; paragraph [0055] [0069]).

Butterfield et al. disclose passive linking between each of the transponder equipped devices and accordingly fail to explicitly recite commands to initiate the connection and transfer of data.

However, it is well known in the art to utilize manual commands to initiate data transfers and wireless connections (DeLaHuerga; paragraphs [0210]-[0213]).

Applicant has amended claim 5 to reflect the "airborne" transmission of data presented in claim 1 as presently amended. This limitation is addressed as presented in the rejection of claim 1 above.

It would have been obvious to one of ordinary skill in the art to have incorporated well known features of patient associated medical device controls, such as command driven functions as presented by DeLaHuerga in to the configuration disclosed by Butterfield et al. with the motivation of providing an accurate simple IV linking and de-linking protocol and simpler interfacing for monitoring and system settings (DeLaHuerga; paragraph [0029]).

Response to Remarks

Applicant's remarks filed 30 December 2008 have been fully considered but they are not persuasive. The remarks will be addressed below in the order in which they appear in the noted response.

Applicant remarks that the combination of Butterfield et al. and DeLa Huerga, does not describe the process defined by claim1 of present application.

Specifically, Applicant remarks:

"The main purpose of Butterfield et al…….is to help verify that correct medical fluid containers are mounted to correct pump channels and connected to the correct patient……the only way to do this and avoid cross-talk confusion is via the medical fluid and not airborne transmissions."

Applicant further remarks:

"Whatever teaching is supplied by De La Huerga, one skilled in the art would be disinclined from making the combination suggested by the Examiner because it would lead to unwanted cross-talk potential..."

In response, Examiner initially notes that Examiner's rejection of the claims as presently amended does not rely on Butterfield et al. in addressing the application of wireless data transmission but Examiner relies on the teachings of De La Huerga in addressing this feature.

In further response, Examiner notes the passages of Butterfield et al. indicated by Applicant including the teachings provided at paragraphs [0034] and [0040]-[0042].

Initially, Examiner notes that at paragraph [0034] Butterfield et al. indicates that data transmission between the devices can be wireless (i.e., "airborne"). Accordingly, Examiner respectfully submits that Butterfield et al. do not indicate that wireless is not to be employed.

As noted by Applicant, Butterfield et al. discusses crosstalk between multiple infusion IV's in which the fluids from multiple sources to a single IV line (Butterfield et al.; paragraphs [0040]-[0041]). The discussion of crosstalk is directed to signals transmitted/propagated through the fluids and a concern the signals may travel along the incorrect fluid line when multiple lines intersect. This problem, Butterfield notes, can be solved with occlusion devices in the lines (Butterfield et al.; paragraph [0040]). Accordingly, the concern relates to fluid transmitted signals in and not to wireless transmission. Butterfield et al. further note that cross talk can be further limited by specific design of the RFID devices (i.e., frequencies etc..

Butterfield et al. clearly indicate that wireless transmission can be used for data transmission and further indicate that the crosstalk problem is related to fluid-based RF transmission as opposed to wireless transmission. DeLaHuerga is employed by Examiner merely to provide evidence that wireless transmission is commonly employed in such applications. Accordingly, Examiner maintains that the combination with is proper and one of ordinary skill in the art would combine the teachings with a reasonable expectation of success.

In conclusion, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 30 December 2008 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Butterfield et al. and DeLaHuerga, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (30 June 2008), and incorporated by reference herein.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. David RINES whose telephone number is (571) 272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GERALD J. O'CONNOR can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/R. D. R./
Examiner, Art Unit 3686
April 13, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686